

SIC 3840

ROUTING RECORD

DATE	FROM	TO	ACTION
9-30-91	SKT	P/S	P/C.
AUG 4 '93	PI	GI	TRANSFER
8-13-93	JMT	CHJ	TRANSFER
1-19-96	JMT	GCR	Transfer
3-18-97	GCR	JMT	Cancel (Inactive status)
2-15-97			RECORDS

REFERENCE TO OTHER APOD  
RECORDS INCLUDING VARIANCES.

085085

3/18/97  
CANCELLED

247256

**CAPPS**

DOCT  
(HNA)



APPLICATION FOR PERMIT TO CONSTRUCT AND PERMIT TO OPERATE  
**SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT**  
9150 Flair Drive, El Monte, CA 91731

FORM 400A

**COMPANY INFORMATION**

LEGAL NAME OF APPLICANT <b>Pacesetter Systems, Inc.</b>		NC/NOV NUMBER _____ INSPECTOR _____ ISSUE DATE _____ IRS OR <input checked="" type="checkbox"/> S.S. NUMBER <table border="1"><tr><td>9</td><td>5</td><td>3</td><td>9</td><td>8</td><td>4</td><td>1</td><td>4</td><td>8</td></tr></table>	9	5	3	9	8	4	1	4	8
9	5	3	9	8	4	1	4	8			
PERMIT TO BE ISSUED TO: (SEE INSTRUCTIONS) <b>Pacesetter Systems, Inc.</b>											
BUSINESS MAILING ADDRESS <b>12884 Bradley Avenue, Sylmar, CA 91342</b>											
TYPE OF ORGANIZATION <input checked="" type="checkbox"/> CORPORATION <input type="checkbox"/> LIMITED PARTNERSHIP <input type="checkbox"/> GOVERNMENT ENTITY <input type="checkbox"/> INDIVIDUAL <input type="checkbox"/> GENERAL PARTNERSHIP <input type="checkbox"/> OTHER											
ARE YOU A SMALL BUSINESS? (SEE INSTRUCTIONS) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		AVERAGE ANNUAL GROSS RECEIPTS: <b>200 M</b> NUMBER OF EMPLOYEES: <b>800</b> IS YOUR BUSINESS 51 PERCENT OR MORE WOMAN/ MINORITY OWNED? (OPTIONAL) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO									
ARE ALL FACILITIES UNDER SAME OWNERSHIP IN CALIFORNIA IN COMPLIANCE WITH FEDERAL, STATE AND LOCAL AIR POLLUTION CONTROL RULES? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO											
ARE YOU THE OWNER OF THE EQUIPMENT UNDER THIS APPLICATION? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO		IRS OR <input type="checkbox"/> S.S. NUMBER OF THE OWNER <table border="1"><tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr></table>									
IF NO, ENTER LEGAL NAME OF OWNER											

**FACILITY INFORMATION**

EQUIPMENT ADDRESS/LOCATION <b>15900 Valley View Court</b> NUMBER / STREET <b>Sylmar</b> CITY OR COMMUNITY <b>CA</b> ZIP CODE <b>91342</b>		FACILITY NAME <b>Pacesetter Systems, Inc.</b> FACILITY ID NUMBER (SEE INSTRUCTIONS) <b>085085</b> 4/12/91
CONTACT PERSON AND TITLE <b>Stephen R. Walters, AQC Inc.</b>		CONTACT TELEPHONE NUMBER <b>(714) 894-5252</b>
TYPE OF BUSINESS AT THIS FACILITY <b>Pacemakers Manufacturing</b>		NUMBER OF EMPLOYEES AT THIS FACILITY: <b>800</b>
BUSINESS TYPE CODE (SEE INSTRUCTIONS) <b>3840</b>		IS THERE A SCHOOL WITHIN 1,000 FEET OF YOUR PROPERTY? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>

**EQUIPMENT INFORMATION**

EQUIPMENT DESCRIPTION (SEE INSTRUCTIONS) <b>Donaldson Standard 1000 SCFM EtO Abator System</b> (refer to attachment for system components)		
APPLICATION FOR: (SEE INSTRUCTIONS) <input checked="" type="checkbox"/> NEW CONSTRUCTION <input type="checkbox"/> MODIFICATION <input type="checkbox"/> CHANGE OF LOCATION <input type="checkbox"/> EXISTING EQUIPMENT OPERATING WITHOUT PERMIT <input type="checkbox"/> CHANGE OF PERMITTEE <input type="checkbox"/> CHANGE OF PERMIT CONDITION <input type="checkbox"/> EXISTING EQUIPMENT WITH EXPIRED PERMIT		ARE YOU SUBMITTING MULTIPLE APPLICATIONS FOR EQUIPMENT IDENTICAL TO THAT DESCRIBED ABOVE? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
HAVE YOU BEEN ISSUED A NOTICE TO COMPLY (NC) OR A NOTICE OF VIOLATION (NOV) FOR THIS EQUIPMENT? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		NUMBER OF EMPLOYEES NEEDED TO OPERATE THIS EQUIPMENT: <b>0</b>
NC NUMBER: _____	NOV NUMBER: _____	NOTICE ISSUE DATE: _____
IF THE EQUIPMENT HAS A PREVIOUS WRITTEN PERMIT, STATE NAME OF PERMITTEE: _____ PREVIOUS PERMIT NUMBER: _____		
FOR NEW CONSTRUCTION OR MODIFICATION, ENTER ESTIMATED COST OF: BASIC EQUIPMENT \$ <b>90,000</b>		AIR POLLUTION CONTROL EQUIPMENT \$ _____
FOR NEW CONSTRUCTION OR MODIFICATION, ENTER ESTIMATED START DATE: <b>4/5/91</b>		ESTIMATED COMPLETION DATE: <b>8/1/91</b>
FOR CHANGE OF PERMITTEE, LOCATION OR CONDITION, ENTER DATE OF OCCURRENCE: _____		FOR EXISTING EQUIPMENT IN OPERATION WITHOUT PRIOR PERMIT, ENTER INITIAL OPERATION DATE: _____
FOR THIS PROJECT, HAS A CALIFORNIA ENVIRONMENTAL QUALITY ACT (CEQA) DOCUMENT BEEN REQUIRED BY ANOTHER GOVERNMENTAL AGENCY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
IF YES, ENTER NAME: _____ AND SUBMIT A COPY IF APPROVED		
DO YOU CLAIM CONFIDENTIALITY OF DATA? (SEE INSTRUCTIONS) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		

I HEREBY CERTIFY, UNDER PENALTY OF PERJURY, THAT ALL INFORMATION CONTAINED HEREIN AND INFORMATION  
SUBMITTED WITH THIS APPLICATION ARE TRUE AND CORRECT

SIGNATURE *Charles K. Stoddard*  
TYPE OR PRINT NAME OF SIGNER

OFFICIAL TITLE OF SIGNER  
**Director, Facility & Maintenance**

**Charles K. Stoddard**

TELEPHONE NUMBER  
**818) 362-6822**

DATE  
**3/26/91**

SCAND (USE ONLY)	APPLICATION NUMBER <b>247256</b>	TYPE <b>B</b>	EQUIPMENT CATEGORY NUMBER <b>00020506</b>	ASSIGNMENT UNIT <b>7</b> ENGINEER	CLASS <b>I</b> III IV	ENF. SECT.
	ENGR. <b>4/12/91</b> A R DATE <b>4/12/91</b>	ENGR. <b>4/12/91</b> A R DATE INITIAL <b>4/12/91</b>	FEE SCHEDULE <b>3700</b>	VALIDATION <b>4/11/91/61</b>	CHECK OR MONEY ORDER NUMBER <b>16769</b>	AMOUNT <b>7100</b>

DISTRIBUTION - WHITE - ENGINEERING - CANARY - ENFORCEMENT - PINK - APPLICANT

(3 OF 3)



**PERMIT TO CONSTRUCT**

9150 FLAIR DRIVE, EL MONTE, CALIFORNIA 91731

Application No.

**247256**

Page 1

Granted as of October 4, 1991

**Legal Owner  
or Operator:**

**ID 85085**

PACESETTER SYSTEMS, INC.  
12884 BRADLEY AVENUE  
SYLMAR, CALIFORNIA 91342  
ATTN: STEPHEN R. WALTERS

**Equipment Location:** 15900 VALLEY VIEW COURT, SYLMAR, CA. 91341

The equipment described below and as shown on the approved plans and specifications are subject to the special condition, or conditions listed.

**Equipment Description:**

**AIR POLLUTION CONTROL SYSTEM CONSISTING OF:**

1. CATALYTIC OXIDIZER/ABATOR, DONALDSON, 7' W. X 5' H. X 21' L., WITH A 80 KW PREHEATER, A HEAT EXCHANGER, A PREFILTER, AND FOUR DCI SURE-SORBER CATALYTIC FILTERS.
2. EXHAUST SYSTEM WITH A 1000 SCFM CENTRIFUGAL AIR BLOWER VENTING TWO ETHYLENE OXIDE STERILIZING SYSTEMS.

**Conditions:**

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN COMPLIANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THE APPLICATION UNDER WHICH THIS PERMIT IS ISSUED UNLESS OTHERWISE NOTED BELOW.
2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.
3. ONLY ONE STERILIZER MAY VENT ITS PRIMARY ETHYLENE OXIDE EXHAUST TO THE CATALYTIC OXIDIZER/ABATOR AT ANY ONE TIME.
4. THE TEMPERATURE OF THE EXHAUST FROM THE CATALYST BED SHALL BE MAINTAINED BETWEEN 300 °F AND 500 °F AS INDICATED BY A PROPER TEMPERATURE GAUGE.
5. RECORDS SHALL BE MAINTAINED TO PROVE COMPLIANCE WITH CONDITION NO. 4. THE RECORDS SHALL BE MADE AVAILABLE TO THE DISTRICT UPON REQUEST.

**FILE COPY**



**PERMIT TO CONSTRUCT**

9150 FLAIR DRIVE, EL MONTE, CALIFORNIA 91731

Application No.  
**247256**  
Page 2

Approval or denial of this application for permit to operate the above equipment will be made after an inspection to determine if the equipment has been constructed in accordance with the approved plans and specifications and if the equipment can be operated in compliance with all Rules of the South Coast Air Quality Management District.

Please notify S. K. TSAI 818/307-3564 when construction of equipment is complete.

This Permit to Construct is based on the plans, specifications, and data submitted as it pertains to the release of air contaminants and control measures or reduce air contaminants. No approval or opinion concerning safety and other factors in design, construction or operation of the equipment is expressed or implied.

This Permit to Construct shall serve as a temporary Permit to Operate provided the Executive Officer is given prior notice of such intent to operate.

This Permit to Construct will become invalid if the Permit to Operate is denied or if this application is cancelled. **THIS PERMIT TO CONSTRUCT SHALL EXPIRE ONE YEAR FROM THE DATE OF ISSUANCE** unless an extension is granted by the Executive Officer.



By

DORRIS M. BAILEY

Principal Office Assistant

DMB/eb

**FILE COPY**

## SCAQML COMPUTER ASSISTED PERMIT PROCESSING (CAPPS)

## FEE DATA - SUMMARY SHEET

Application No : 247256  
 Previous Permit No:

IRS/SS No: 000-00-0000  
 Previous Application No:

Company Name : SIEMENS PACESETTER INC Facility ID: 085085  
 Equipment Street: 15900 VALLEY VIEW CT, SYLMAR, CA 91392  
 Equipment Desc.: AFTERBURNER, CATALYTIC

Equipment Type : CONTROL Fee Charged by: C-CAT  
 B-CAT NO. : 000000 C-CAT NO. : 06 Schedule: D  
 Facility Zone : 7 Deemed Compl. Date: 5/15/1991 PUBLIC NOTICE: NO

APPLICATION FILING FEE (PRIOR TO 7/1/90 & PLANS FEE) ..... \$ 0.00  
 EVALUATION FEE PRE-PAID (POST 7/1/90) ..... \$ 0.00

Evaluation Type: PERMIT TO OPERATE (PO) Small Business?: NO  
 Disposition : CANCEL PO - DON'T REFUND FEE P/O NO P/C Penalty?: NO  
 Reference App. No: Similar Permit Unit?: NO

1. PERMIT PROC. FEE* (APPL FILED PRIOR TO 7/1/90) SUMMARY PERMIT		
FEE RATES * \$ 3,700.00 LESS FILING FEE PAID \$	.....	\$ 0.00
2. EIR .....		\$ 0.00
3. AIR QUALITY ANALYSIS (TABLE II FEE) .....		\$ 0.00
4. HEALTH RISK ASSESSMENT (TABLE II FEE) .....		\$ 0.00
5. SIGNIFICANT PROJECT REVIEW (TABLE II FEE) .....		\$ 0.00
6. SOURCE TEST REVIEW: (RULE 306(i) FEE) \$1600 +		
[ NO HRS @ \$75/HR] .....	5/9/91	\$ 0.00
7. CEMS REVIEW (TABLE II FEE) .....		\$ 0.00
8. TIME AND MATERIALS (FOR PLAN APPLICATIONS ONLY)		
0.00 HRS @ \$ 75.00/HR .....		\$ 0.00
9. PERMIT PROCESSING FEE ADJUSTMENT** ADDITIONAL FEE		
TABLE I FEE* \$ 3,700.00 LESS EVAL. FEE PAID \$	...	\$ 3,700.00
10. OTHER FEES** (INCLUDING CANCELLATION) .....		\$ -3,700.00
<b>TOTAL:</b>		<b>\$ 0.00</b>


COMMENTS: FEE WAS PAID WHEN A/N SUBMITTED. A/N IS ALREADY INACTIVATED BY THE CUSTOMER SERVICE. A NEW I.D. # 103609 WAS ASSIGNED AND EQUIP PERMITTED UNDER A/N 298970.

Recommended By: GCR DATE: 3/18/1997 REVIEWING ENG: \_\_\_\_\_ DATE: \_\_\_\_\_

\* ADJUSTED FOR SMALL BUSINESS, IDENTICAL EQUIPMENT, AND P/O NO P/C PENALTY

\*\* ADJUSTED FOR INCORRECT FEE SUBMITTAL, SMALL BUSINESS, IDENTICAL EQUIPMENT, AND P/O NO P/C PENALTY

**SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT**  
**OFFICE OF STATIONARY SOURCE COMPLIANCE**  
**MEMORANDUM**

**DATE:** July 30, 1993  
**TO:** William Thompson  
**FROM:** Mohsen Nazemi   
**SUBJECT:** Applications for ETO Sterilizers

As we have previously discussed, I am transferring herewith all the pending applications for ETO sterilizing facilities that are presently in my group. Although, the responsibility for implementation and compliance will now be your responsibility, any necessary rule-making programs for amending or replacing Rule 1405 will continue to reside with my Toxics group.

The applications being transferred are as follows:  
Pacesetter Systems - 122339, 173696, 182873

MN:HNH

cc: L. Lockie  
C. Coy  
V. Gonzales

## ENGINEERING DIVISION...MEMORANDUM

TO FILE	FROM RGC	DATE 7-26-93
REFERENCE T/C with Ron Romesh		PERMIT APPL. NO.

SUBJECT

- ① S/T reg. for San Fernando Rd Facility
- ② Status of Valley View Const Facility

Left message to Ron Romesh, 818-362-6822  
x 2573.

Mr. Romesh informed me that they decided to change source test contractors to Chips Env. I advised Mr. Romesh of the S/T reg. for HCl, Chlorine, Phosgene + halogenated organics per T/C conds. I told him that the S/T reg. might be waived depending on their Eto & freon usage. He would determine the annual usage for the San Fernando Rd facility.

Mr. Romesh also told me that the use 1290 Eto & the rest is Freon 1288 at the San Fernando Rd facility. The sterilizers will no longer be used when the Valley View facility is started up. He said that the new facility which will use pure Eto will be started-up in 4-6 mos. He was not sure if the existing sterilizers would be sold to the new owners. He said that currently the facility they occupy is owned by the new owners who may acquire the <sup>freon</sup> sterilizers. He added that the new sterilizers were installed but were not yet started-up.

**FEE DATA - SUMMARY SHEET**

Application No : 247256

IRS/SS No:

Previous Permit No:

Previous Application No:

Company Name : PACESETTER SYSTEMS INC

Facility ID: 005085

Equipment Street: 15900 VALLEYVIEW CT, SYLMAR, CA 91342

Equipment Desc. : AFTERBURNER, CATALYTIC

B-CAT NO. : 000000 C-CAT NO. : 06 Schedule: D PUBLIC NOTICE REQUIRED: NO

APPLICATION FILING FEE (PRIOR TO 7/1/90 &amp; PLANS FEE) ..... \$

EVALUATION FEE PRE-PAID (POST 7/1/90) ..... \$ 3,700.00

Evaluation Type: PERMIT TO CONSTRUCT (PC)

Small Business?: NO

Disposition: APPROVE PC

P/O NO P/C Penalty?: NO

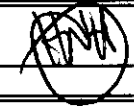
Reference App. No:

Identical Permit Unit?: NO

1. PERMIT PROC. FEE* (APPL FILED PRIOR TO 7/1/90) .....	1. \$	0.00
2. EIR .....	2. \$	0.00
3. AIR QUALITY ANALYSIS .....	3. \$	0.00
4. HEALTH RISK ASSESSMENT .....	4. \$	0.00
5. SIGNIFICANT PROJECT REVIEW .....	5. \$	0.00
6. SOURCE TEST REVIEW .....	6. \$	0.00
7. CEMS REVIEW .....	7. \$	0.00
8. TIME AND MATERIALS (FOR PLANS APPLICATIONS ONLY) ....	8. \$	0.00
9. PERMIT PROCESSING FEE ADJUSTMENT**		
ADDITIONAL FEE .....	9. \$	0.00
10. OTHER FEES** (INCLUDING CANCELLATION) .....	10. \$	0.00

TOTAL: \$ 0.00

COMMENTS: FOR PERMIT WORDING AND CONDITIONS SEE PAGE 1 & 2 OF PROCESSING SHEETS.

Recommended By: SKT DATE: 9/30/1991 REVIEWING ENG: 

DATE: OCT 1 1991

\* ADJUSTED FOR SMALL BUSINESS, IDENTICAL EQUIPMENT, AND P/O NO P/C PENALTY

\*\* ADJUSTED FOR INCORRECT FEE SUBMITTAL, SMALL BUSINESS, IDENTICAL EQUIPMENT, AND P/O NO P/C PENALTY



SCAQMD COMPUTER ASSISTED PERMIT PROCESSING (CAPPS)

**AEIS DATA SHEET**

(For P/C Only)

Company Name **PACESETTER SYSTEMS INC**

Facility ID **085085**

Equipment Address **15900 VALLEYVIEW CT, SYLMAR CA 91342**

APPLICATION NUMBER	<b>247256</b>
ESTIMATED COMPLETION DATE	<b>12/01/1991</b>
EQUIPMENT B-CAT	<b>000000</b>
EQUIPMENT C-CAT	<b>06</b>
EQUIPMENT DESCRIPTION	<b>AFTERBURNER, CATALYTIC</b>
EQUIPMENT TYPE	<b>C</b>
SCHEDULE/STEP	<b>3/C</b>

Supervisor's Name: \_\_\_\_\_



Engineers Name: **SUSAN K TSAI**

Date: **9/30/1991**

Review Date: **OCT 1 '91**

# South Coast Air Quality Management District

## Facility Equipment List Report

Facility: 85085 SIEMENS PACESETTER INC  
 Last Inspection: 02/19/1993  
 SIC: 3845  
 Inspector:  
 Location Address: 15900 VALLEY VIEW CT, SYLMAR 91392-9221  
 Mailing Address: 15900 VALLEY VIEW CT, SYLMAR 91392-9221  
 Comment:

MR: 0601  
 TS: NONE  
 Assignment No.

Contact: C. K. STODDARD (818) 3626822  
 Quarter: 0001 - inspect in 4th quarter, every year  
 On Hold:  
 Suspended:  
 Team:

Application No.	Permit No.	Permit Issue Date	Permit Status	Equipment Category	BCAT/CCAT Description	Application Date	Application Status
278881	D71408	03/19/1993	INACTIVE	000321	BCAT	03/02/1993	PERMIT TO OPERATE GRANTED
259031	D46563	01/14/1992	INACTIVE	44	CCAT	12/04/1991	PERMIT TO OPERATE GRANTED
259032	D46565	01/14/1992	INACTIVE	000284	BCAT	12/04/1991	PERMIT TO OPERATE GRANTED
258822	D46387	01/06/1992	INACTIVE	000241	BCAT	12/02/1991	PERMIT TO OPERATE GRANTED
254025	D46372	01/06/1992	INACTIVE	000241	BCAT	07/24/1991	PERMIT TO OPERATE GRANTED
254026	D46384	01/06/1992	INACTIVE	000241	BCAT	07/24/1991	PERMIT TO OPERATE GRANTED
254027	D46311	01/02/1992	INACTIVE	000241	BCAT	07/24/1991	PERMIT TO OPERATE GRANTED
254967	D45011	11/06/1991	INACTIVE	000411	BCAT	08/15/1991	PERMIT TO OPERATE GRANTED
255051	D43549	10/02/1991	INACTIVE	043901	BCAT	08/16/1991	PERMIT TO OPERATE GRANTED
247254		00/00/0000		000289	BCAT	04/12/1991	APPLICATION CANCELLED, REFUND ALL FEES
247255		00/00/0000		000289	BCAT	04/12/1991	APPLICATION CANCELLED, REFUND ALL FEES
247256		00/00/0000		06	CCAT	04/12/1991	APPLICATION CANCELLED, REFUND ALL FEES

New Alaris were filed under ID 103609 and provided.

See ID # 103609

# South Coast Air Quality Management District

## Facility Equipment List Report

Facility: 103609 PACESETTER INC, A ST JUDE MEDICAL CO  
Last Inspection: 02/19/1993  
SIC: 3845  
Inspector:  
Location Address: 15900 VALLEY VIEW CT, SYLMAR 91392-9221  
Mailing Address: 15900 VALLEY VIEW CT, SYLMAR 91392-9221  
Comment:

MR: 0601  
TS: NONE  
Assignment No.

Contact: C. K. STODDARD (818) 3626822  
Quarter: 0100 - inspect in 2nd quarter, every year  
On Hold:  
Team:  
Suspended:

Application No.	Permit No.	Permit Issue Date	Permit Status	Equipment Category	BCAT/CCAT Description	Application Date	Application Status
298970	D87020	12/09/1994	ACTIVE	06	CCAT AFTERBURNER, CATALYTIC	12/06/1994	PERMIT TO OPERATE GRANTED
298971	D87021	12/09/1994	ACTIVE	000289	BCAT STERILIZING EQUIPMENT	12/06/1994	PERMIT TO OPERATE GRANTED
298972	D87022	12/09/1994	ACTIVE	000289	BCAT STERILIZING EQUIPMENT	12/06/1994	PERMIT TO OPERATE GRANTED
298986	D86984	12/07/1994	ACTIVE	000321	BCAT TANK, SURFACE PREPARATION - OTHER ACIDS	12/06/1994	PERMIT TO OPERATE GRANTED
298988	D86985	12/07/1994	ACTIVE	043901	BCAT I C E (50-500 HP) EM ELEC GEN-DIESEL	12/06/1994	PERMIT TO OPERATE GRANTED
298989	D86986	12/07/1994	INACTIVE	000411	BCAT SOLDERING MACHINE	12/06/1994	PERMIT TO OPERATE GRANTED

**South Coast Air Quality Management District**  
**Engineering Division**  
**New Source Review Regulation XIII Data Sheet**

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**APPLICATION NUMBER** : 247256  
**FACILITY I.D. NUMBER**: 085085  
**FACILITY NAME** : PACESETTER SYSTEMS INC  
**FACILITY ADDRESS** : 15900 VALLEYVIEW CT  
**CITY** : SYLMAR **STATE**: CA **ZIP**: 91342-0000

**PERMIT TYPE** : PC **PREVIOUS APPLICATION NUMBER**:  
**DEEMED COMPLETE**: 5/15/1991

**PROCESSING DECISION FOR APPLICATION**:  
**TRANSACTION CODE**: INSTALL  
**ENGINEER**: SUSAN K TSAI

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**EMISSION DATA: ROG**

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Max Daily (Uncontrolled)	:		lbs/day
Max Daily (Controlled)	:		lbs/day
Positive Balance	:	0	lbs/day
30 Day Average (Controlled)	:		lbs/day
Annual (Controlled)	:		lbs/year

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**SUPERVISOR'S APPROVAL:**



**SUPERVISOR'S REVIEW DATE:** OCT 1

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**SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT****ENGINEERING DIVISION****APPLICATION PROCESSING AND CALCULATIONS**

PAGES	PAGE
7	1
APPL. NO.	DATE
247254-6	9-25-91
PROCESSED BY	CHECKED BY
AOC	SKT

**PACESETTER SYSTEMS, INC.**  
12884 BRADLEY AVENUE  
SYLMAR, CA 91342

**EQUIPMENT LOCATION:**

15900 VALLEY VIEW COURT, SYLMAR, CA 91342

**EQUIPMENT DESCRIPTIONS:****APPLICATION NO. 247254**

ETHYLENE OXIDE STERILIZATION SYSTEM NO. 1 CONSISTING OF :

1. STERILIZER NO. 1, GETINGE, MODEL NO. 8440AR1, 2'-11" W. X 4'-9" H. X 5'-0" L.
2. STEAM GENERATOR, 60 KW, WITH 201,000 BTU PER HR OUTPUT.

**APPLICATION NO. 247255**

ETHYLENE OXIDE STERILIZATION SYSTEM NO. 2 CONSISTING OF :

1. STERILIZER NO. 2, GETINGE, MODEL NO. 8430AR1, 2'-2" W. X 3'-0" H. X 5'-0" L.
2. STEAM GENERATOR, 60 KW, WITH 201,000 BTU PER HR OUTPUT.

**APPLICATION NO. 247256**

AIR POLLUTION CONTROL SYSTEM CONSISTING OF :

1. CATALYTIC OXIDIZER/ABATOR, DONALDSON, 7' W. X 5' H. X 21' L., WITH A 80 KW PREHEATER, A HEAT EXCHANGER, A PREFILTER, AND FOUR DCI SURE-SORBER CATALYTIC FILTERS.
2. EXHAUST SYSTEM WITH A 1000 SCFM CENTRIFUGAL AIR BLOWER VENTING TWO ETHYLENE OXIDE STERILIZING SYSTEMS.

**SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT****ENGINEERING DIVISION****APPLICATION PROCESSING AND CALCULATIONS****PAGES**

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**PAGE**

2

**APPL. NO.**

247254-6

**DATE**

9-25-91

**PROCESSED BY**

AQC

**CHECKED BY**

SKT

**CONDITIONS****APPLICATIONS NO. 247254 & 247255**

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN ACCORDANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THIS APPLICATION UNDER WHICH A PERMIT IS ISSUED UNLESS OTHERWISE NOTED BELOW.
2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.
3. THIS EQUIPMENT SHALL NOT BE OPERATED UNLESS THE STERILIZER EXHAUST IS VENTED TO AN AIR POLLUTION CONTROL DEVICE WHICH IS IN FULL USE AND WHICH HAS BEEN ISSUED AN PERMIT TO CONSTRUCT BY THE EXECUTIVE OFFICER.
4. NO MORE THAN 16 POUNDS OF ETHYLENE OXIDE GAS SHALL BE CHARGED TO THE STERILIZERS AT THIS FACILITY IN ANY ONE DAY.
5. NO MORE THAN 4000 POUNDS OF ETHYLENE OXIDE GAS SHALL BE USED IN THIS FACILITY IN ANY ONE CALENDER YEAR.

**APPLICATION NO. 247256**

1. OPERATION OF THIS EQUIPMENT SHALL BE CONDUCTED IN ACCORDANCE WITH ALL DATA AND SPECIFICATIONS SUBMITTED WITH THIS APPLICATION UNDER WHICH A PERMIT IS ISSUED UNLESS OTHERWISE NOTED.
2. THIS EQUIPMENT SHALL BE PROPERLY MAINTAINED AND KEPT IN GOOD OPERATING CONDITION AT ALL TIMES.
3. ONLY ONE STERILIZER MAY VENT ITS PRIMARY ETHYLENE OXIDE EXHAUST TO THE CATALYTIC OXIDIZER/ABATOR AT ANY ONE TIME.
4. THE TEMPERATURE OF THE EXHAUST FROM THE CATALYST BED SHALL BE MAINTAINED BETWEEN 300°F AND 500°F AS INDICATED BY A PROPER TEMPERATURE GAGE.
5. RECORDS SHALL BE MAINTAINED TO PROVE COMPLIANCE WITH CONDITION NO. 4. THE RECORDS SHALL BE MADE AVAILABLE TO THE DISTRICT UPON REQUEST.

**SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT****ENGINEERING DIVISION****APPLICATION PROCESSING AND CALCULATIONS**

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APPL. NO.	DATE
247254-6	9-25-91
PROCESSED BY	CHECKED BY
AQC	SKT

**BACKGROUND**

Pacesetter Systems, Inc. manufactures heart pacemakers and their facility is presently located at 12884 Bradley Avenue in Sylmar, CA. Their operations will be completely moved to another facility at 15900 Valley View Court in Sylmar, CA. Pacesetter plans to purchase two new sterilizers and abator system (catalytic oxidizer) to conduct their sterilization operations in this new facility.

These new sterilizers will be constructed in a fire-proof sterilization room at the Valley View facility, and utilize 100% ethylene oxide (EtO) to sterilize components of the pacemakers, pacers and leads. The abator system will control all EtO emissions from the operation of the sterilizers, and has an expected efficiency of 99.9%. Complete aeration of the product loads will be conducted inside the sterilizers, so any EtO residue left upon completion of sterilization will be vented to the abator. The room in which the sterilizers are situated will be continuously vented to the abator as well to control any fugitive EtO.

A typical load of product will contain equal quantities of pacers and leads. Pacers are constructed of a Titanium can with an epoxy connector top. Leads are made of silicone tubing over a metal conductor with a connector that fits into the pacer connector on one end and a metal electrode on the other. Each pacer or lead is packaged in two 0.025" thick, vacuum formed XT Polymer trays; the inner tray measures 4.25" x 7.25", and the outer one is 5" x 8". The 32 cubic foot sterilizer will typically hold 400 packages, and the 69 cubic foot unit will hold 1400 packages.

Ethylene oxide is a carcinogenic air contaminant. Permitting and operation of the sterilizers are subject to the requirements of Rules 1401 and 1405, respectively.

Applications for Permits to Construct the sterilizers and abator system were submitted on April 10, 1991.

**PROCESS DESCRIPTION**

The sterilizers use 100% ethylene oxide (EtO) to sterilize components of heart pacemakers: pacers and leads. The total EtO usage is projected to be 5.65 pounds per day for both sterilizers.

**SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT****ENGINEERING DIVISION****APPLICATION PROCESSING AND CALCULATIONS**

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Batch loads of pacers and leads are placed in the sterilizers, and experience a 22 hour sterilization cycle. The sequence of operation of the sterilization cycles is as follows:

- a. The load is heated by recirculating the chamber air for a pre-set time period of approximately 20 minutes.
- b. The chamber is evacuated by the vacuum pump at a pre-set rate until a pre-set vacuum level is achieved.
- c. The chamber is held under vacuum for 10 minutes to determine if any leaks exist.
- d. Compressed nitrogen gas is admitted to the chamber at a pre-set pressure. Chamber is re-evacuated, and charged again with nitrogen gas for a pre-set number of pulses.
- e. The load is humidified with pulse injections of steam to a pre-set absolute pressure level.
- f. The load is held at temperature and humidity for a pre-selected pre-conditioning time.
- g. Ethylene oxide (EtO) gas is admitted to the chamber at a pre-set rate until a pre-set pressure is achieved. Nitrogen gas is admitted to chamber at a pre-set rate until a pre-set pressure is achieved. A subsequent charge of nitrogen gas into chamber purges gas lines of EtO.
- h. Chamber pressure is maintained for the pre-selected sterilizing time period.
- i. Primary exhaust of the chamber gases commences through the ventilation system at a pre-set rate to an abator (a catalytic control device) where 99.9% of EtO in the primary chamber exhaust is oxidized to carbon dioxide and water.
- j. Chamber is evacuated to pre-set vacuum level. Nitrogen gas is admitted to chamber at a pre-set rate until pre-set pressure is attained (Steps i & j are repeated at least 2 additional times).
- k. Complete chamber aeration commences by alternating a pre-set number of vacuum and air purges.
- l. Air is admitted to the chamber through the bacterial retentive air filter until ambient atmospheric pressure is achieved.



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The sterilization chamber is heated by recirculating water through a jacket lining the ceiling, walls, and floor. The water is heated by steam provided by a 60 KW electric steam generator. A centrifugal-type fan is fitted to the roof of the chamber to circulate internal air and gases, and powered by an external electric motor. All chamber air and gases are exhausted through a ventilation system ducted to the ethylene oxide abator system.

In the abator system, the ethylene oxide contaminated air is passed through 4 catalytic filters containing a catalyst made up of a manganese dioxide and copper oxide mixture. The ethylene oxide adsorbs to the catalyst, and is oxidized to carbon dioxide and water according to the following equation:



Prior to introducing EtO to the abator system, there is a preheat cycle of approximately 45 minutes to bring the system to an operating temperature of 300 degrees Fahrenheit (after initial start up, the abator will operate continuously). The fan motor and heater are energized and the dampers are positioned in the preheat mode. The warm air heats up the catalytic beds. When the sensor on the catalytic beds senses a temperature of 300 degrees Fahrenheit, the system will end the preheat cycle and open the EtO feed valve. Due to the release of heat during the oxidation of ethylene oxide, the heater is used very little once the catalytic beds have reached the operating temperature.

Air from the sterilizer chambers and sterilization room are pulled into the abator system by a 1000 scfm centrifugal fan. Any particulate in the incoming air is removed by the Dustfoe prefilters. The air then passes through a recuperative heat exchanger, heating coils, and then into the catalytic beds. The EtO free air proceeds through the fans, and a portion of the discharge is recirculated to the hot side of the recuperative heat exchanger to preheat incoming air. The amount of flow directed to the heat exchanger is controlled depending upon the temperature of the catalytic beds. In addition, a temperature control switch will close the EtO feed valve should the catalytic bed temperature rise above 550 degrees Fahrenheit.

Safety mechanisms are provided to restrict the EtO feed valve from opening unless the following criteria are satisfied:

1. Catalytic bed temperature at a minimum of 300 degrees Fahrenheit
2. Catalytic bed temperature below 550 degrees Fahrenheit
3. Minimum air flow rate of 900 cfm
4. Safety blow-out pan properly sealed

**SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT****ENGINEERING DIVISION****APPLICATION PROCESSING AND CALCULATIONS**

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**EMISSION AND RISK CALCULATIONS****Ethylene Oxide Emission Calculations:**

Operating Schedule: 8 hrs/day, 5 days/week, 52 weeks/yr

Maximum Amount of EtO usage: 16 lb/day

$$R1 = \text{uncontrolled emissions} = 16 \text{ lbs/day}$$

$$R2 = \text{controlled emissions} = 16 \text{ lbs/day} \times (1 - 0.999) \\ = 0.016 \text{ lbs/day}$$

$$\text{Yearly average emission} = 0.016 \text{ lbs/day} \times (261/365) \\ = 0.011 \text{ lb/day}$$

**Risk Assessment Calculation:**

$$\text{MICR} = Q \times (X/Q) \times U \times \text{MP}$$

- MICR - Maximum Individual Cancer Risk  
Q - Emission Rate of EtO in lb/day  
X/Q - EtO Concentration (Tables 3 & 4, Rule 1401)  
U - Unit Risk Factor for EtO (Table 1, Rule 1401)  
MP - Multiple Pathway Adjustment Factor

**Risk at the Nearest Residential Area:**

$$Q = 0.011 \text{ lb/day} \\ X/Q = 0.673 \text{ [ug/m}^3\text{]} / \text{[lb/day]} \\ U = 0.000088 \text{ [1/(ug/m}^3\text{)]} \\ \text{MP} = 1$$

$$\text{MICR} = 0.011 \times 0.673 \times 0.000088 \times 1 \\ = 0.65 \times 10^{-6}$$

**Risk at the Commercial/Industrial Locations:**

$$Q = 0.011 \text{ lb/day} \\ X/Q = 3.01 \text{ [ug/m}^3\text{]} / \text{[lb/day]} \\ U = 0.000088 \text{ [1/(ug/m}^3\text{)]} \\ \text{MP} = 1$$

$$\text{MICR} = 0.011 \times 3.01 \times 0.000088 \times 1 \\ = 2.9 \times 10^{-6}$$

Multiplication factor for adjustment for land use considerations at commercial/industrial locations is 0.15.

$$\text{Adjusted Risk} = 2.9 \times 10^{-6} \times 0.15 = 0.44 \times 10^{-6}$$

**SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT****ENGINEERING DIVISION****APPLICATION PROCESSING AND CALCULATIONS**

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The off-site commercial/industrial risk times 0.15 is less than one-in-one million and the nearest residential area risk is also less than one-in-one million, therefore, the facility is considered to have passed the screening assessment.

**RULE EVALUATION**

Rule 212 Compliance with this rule is expected.

The maximum individual cancer risk is less than one-in-one million.

Rule 401 No visible emissions expected.

Rule 402 No nuisance expected.

Reg. XIII Compliance with this regulation is expected.

The air pollution control system satisfied the BACT requirement.

Rule 1401 The maximum individual cancer risk (MICR) is less than one-one in million, compliance with this rule is expected.

Rule 1405 Compliance with this rule is expected.

All exhaust of EtO must be vented an control device with 99.6% efficiency. The abator system is expected to achieve 99.9% efficiency.

**RECOMMENDATIONS**

Based on the above evaluation, conditional Permits to Construct are recommended for Applications No. 247254, 247255, and 247256.



**Air Quality Consultants, Inc.**  
15541 Commerce Lane  
Huntington Beach, CA 92649

TEL: (714) 894-5252  
FAX: (714) 893-2322

June 6, 1991

Milton Cohen  
South Coast AQMD  
9150 Flair Drive  
El Monte, CA 91731

Re: Sterilizer and Abator System Permit Applications for  
Pacesetter Systems, Inc.  
15900 Valley View Court  
Sylmar, CA 91342

Dear Mr. Cohen:

In response to our phone conversation on 5/15/91, as well as your written request faxed on 5/21/91, we have outlined below the additional information to complete the applications submitted for Pacesetter Systems.

Pacesetter Systems is moving to a new facility at the above referenced address, and plans to install two ethylene oxide (EtO) sterilizers and one abator system. In compliance with the most current Rule 1405, Pacesetter will utilize non-CFC base ethylene oxide (100% EtO) in these new units.

In addition, the following measures will be taken to maximize the containment and control of ethylene oxide emissions. The sterilizers will be contained exclusively inside a sterilization room. Each sterilizer will exhaust chamber gases from respective sterilizing time periods to the abator one at a time. Aeration of each load of product will be performed within the sterilizers. Also, sterilization room air will be continuously vented to the abator to control any fugitive ethylene oxide.

A typical load of product will contain equal quantities of pacers and leads. Pacers are constructed of a Titanium can with an epoxy connector top. Leads are made of silicone tubing over a metal conductor with a connector that fits into the pacer connector on one end and a metal electrode on the other. Each pacer or lead is packaged in two 0.025" thick, vacuum formed XT Polymer trays; the inner tray measures 4.25" x 7.25", and the outer one is 5" x 8". The

small 30 cubic foot sterilizer will typically hold 400 packages, and the large unit, 1400 packages.

The abator system is designed to contain 4 catalytic cells positioned in series; each cell has dimensions of 24" x 24" x 12", and ninety pounds of catalyst. The catalyst is made up of a manganese dioxide and copper oxide mixture (MSDS enclosed). In addition, although the abator was designed with the capacity to accommodate an additional sterilizer, presently no other sterilizer will be installed.

We hope this information is helpful in your review of these applications. If there are any questions, please do not hesitate to call.

Sincerely,

A handwritten signature in cursive script that reads "Steve R. Walters".

Steve Walters  
Project Engineer

Enclosure

cc: Chuck Stoddard, Pacesetter Systems  
Terry Williams, Pacesetter Systems



South Coast  
AIR QUALITY MANAGEMENT DISTRICT

9150 FLAIR DRIVE, EL MONTE, CA 91731 (818) 572-6200

DATE: 5-15-91

FACESETTER SYSTEMS, INC  
12884 BRADLEY AVENUE  
SYLMAR CA 91342

ATTENTION: MR. STEPHEN R. WALTERS

The South Coast Air Quality Management District has received your applications and made the following determination:

Appl. No.	Determination Number	Equipment Description
247254	(2)	ETHYLENE OXIDE STERILIZER NO. 1
247255	(2)	ETHYLENE OXIDE STERILIZER NO. 2
247256	(2)	ETO CATALYTIC INCINERATOR

TO BE LOCATED AT

Deter. No. 15900 VALLEY VIEW COURT  
SYLMAR CA 91342

- (1) The information you submitted with this application or in your latest submittal is complete; however, some clarifying data may still be needed. The acceptance of your application as complete indicates that sufficient information is on file to begin an evaluation, but does not imply that a permit has been approved.
- (2) The information you submitted with this application or in your latest submittal, is NOT complete. Specific details of the information required to process your application are enclosed. Please submit the requested information by the date shown on the attached form.
- (3) The information submitted with this application is not complete. Additional information was previously requested per District letter dated \_\_\_\_\_ (copy attached). If specific detailed information as outlined on the attached Additional Information Request Sheet is not submitted by \_\_\_\_\_, your application may be denied pursuant to Rule 210.

If you have any questions concerning your application, please contact MILTON CIVEN at (818) 572-6229.

Very truly yours,

for Dave Schvien  
Senior Engineering Manager

MN:ai

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT

MEMORANDUM

DATE: 5-15-91

TO: MR. STEPHEN R. WALTERS, RQC INC.

FROM: MILTON COHEN, SCAQMD

SUBJECT: ADDITIONAL INFORMATION REQUIRED IN REGARD  
TO PAGESSETTEN SYSTEMS, INC.

AS PER TELEPHONE CONVERSATION ON 5-15-91  
PLEASE SUBMIT THE FOLLOWING:

1. DIMENSIONS OF THE CATALYTIC BED
2. CHEMICAL COMPOSITION OF CATALYTIC BED.
3. MATERIAL COMPOSITION OF STERILIZED PRODUCT AND PACKAGING.
4. STERILIZED PRODUCT AERATION ROOM, DETAILS AND OPERATION, PROVIDED SUCH ROOM IS REQUIRED.
5. INDICATE MAXIMUM NUMBER OF CYCLES ANY ONE STERILIZER WILL OPERATE IN ANY ONE DAY.
6. STATE THE INSTALLATION AND OPERATIONAL STATUS OF AN INDICATED THIRD (30 CUBIC FOOT) STERILIZER.

II

Pacesetter Systems, Inc.

Donaldson Standard 1000 SCFM EtO Abator System  
Permit Application Supplemental

Contains the following:

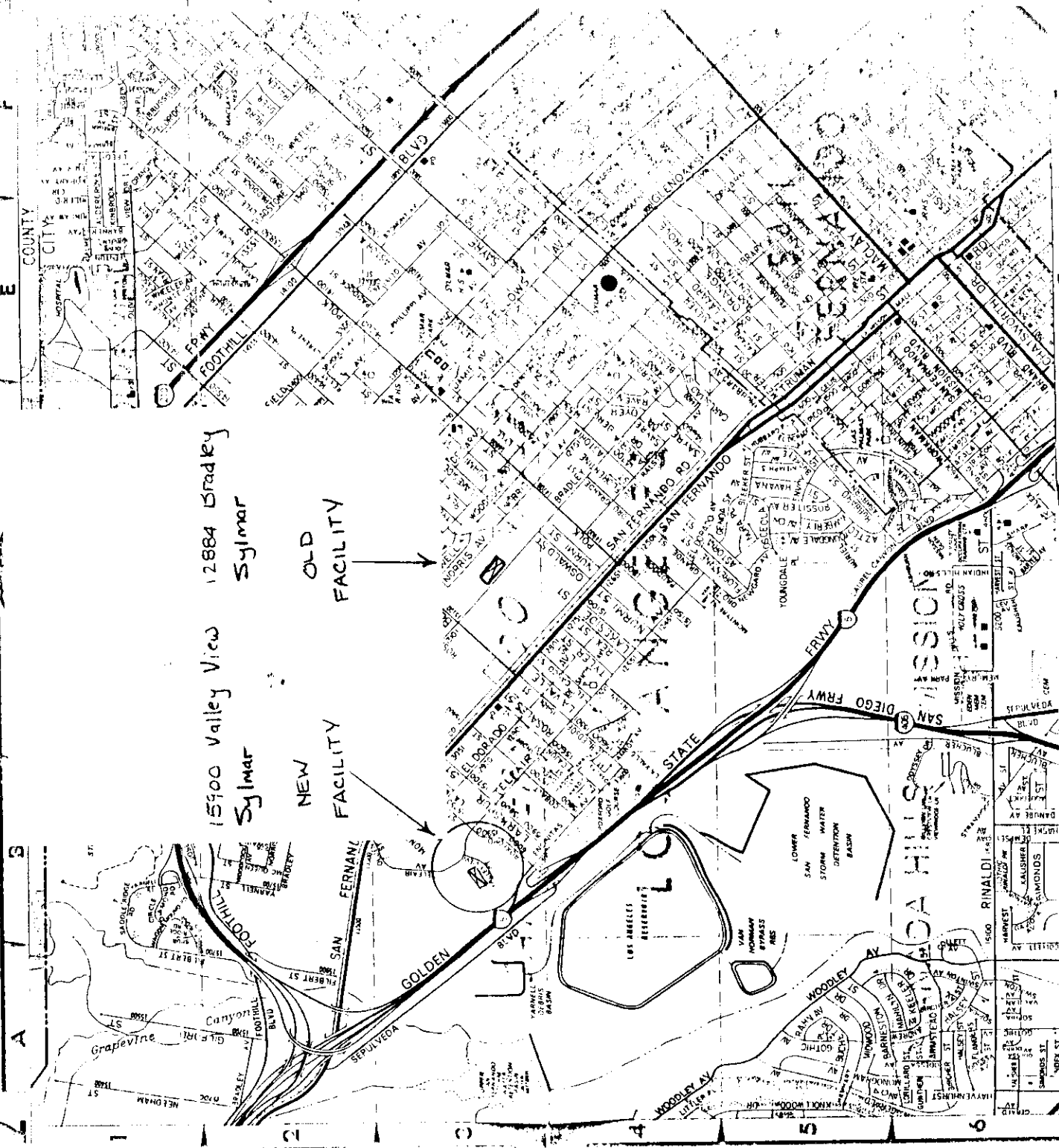
1. Description of System Operation
2. Description of System Components
3. Attachment #1 - Site Plan
4. Attachment #2 - System Diagram



SEE MAP

E COUNTY

SEE MAP



15900 Valley View  
Sylmar

NEW  
FACILITY

OLD  
FACILITY

SEE MAP

TECHNICAL PROPOSAL TP-EtO-912-07

to

PACESETTER SYSTEMS, INC.

1.0 SCOPE

The Donaldson EtO Abator System illustrated on DCI Drawing 6262P0169 Sheet 1 is designed to remove ethylene oxide from the exhaust stream of three sterilizers. The 1000 SCFM EtO Abator proposed can handle EtO flows above 0.34 lb/min. for the first two minutes of the vent cycle and 0.34 lb/min. continuously thereafter. The system is also designed to handle 1000 CFM from the aeration cabinets.

The system is designed to dilute the exhaust stream EtO concentration to the Abator to less than 5,000 ppm by volume. This provides a safe level for operation. The EtO concentration is well below the minimum explosion limit of EtO in air and the temperature created by the reaction is not excessive. The EtO Abator is instrumented to assist in maintaining conditions within economical and safe conditions.

The present operating condition for the sterilizers are as follows:

<u>Sterilizer (ft<sup>3</sup>)</u>	<u>EtO Charge (lbs)</u>	<u>Cycles/day</u>
69	3.3	1
32.5	1.5	1
✓ 30 ERROR	1.45	1

Donaldson is proposing a 1000 SCFM system which will handle 0.34 lbs/minute of EtO continuously. To insure that we do not overheat the Abator during the first vent cycle, the EtO flow to the Abator must be reduced to this level. This can either be controlled by the sterilizer pump down rate or by using a valve to limit the flow.

## 2.0 PROPOSED SYSTEM OPERATION

Ref: DCI Flow Schematic, Drawing No. 6262P0169, Sheet 2.

### 2.1 Initial Start-up/Pre-heat

Prior to introducing any EtO into the system, the unit must be preheated. The preheat cycle takes approximately 45 minutes to bring the system to an operating temperature of 300°F. The fan motor and heater are energized and the dampers are positioned in the preheat mode. The heated air in turn heats the catalyst. A temperature indicating switch located at the catalytic bed senses the temperature of the air stream, when the temperature reaches 300°F, its contacts will energize a permissive switch (relay) taking the unit out of the preheating mode and energizing the EtO feed valve. Once the catalyst bed reaches operating temperature, the heater is used very little as the catalytic reaction produces heat which is used to maintain the bed temperature.

### 2.2 Normal Operation

The DCI EtO Abator System effectively removes ethylene oxide through catalysis. It removes EtO from the airstream in accordance with the equation:



Air is pulled into the system by the fan from the aeration room, or fresh air intake. Particulate is removed as the air passes through the Dustfree prefilters. The air then enters the recuperative heat exchanger and over the heating coil where it is heated to 300°F. From here, it enters the catalytic beds where the EtO is reduced to CO<sub>2</sub>, water vapor, and heat. The EtO free air proceeds through the fans. A portion of the discharge flow of the fan is

ducted through the hot side of the recuperative heat exchanger to preheat incoming air prior to venting. As the catalyst temperature increases, less air is circulated through the recuperative heat exchanger, and more air exits directly from the fan.

Should the catalyst outlet temperature rise above 550°F, a temperature switch will cause the EtO feed valve to close stopping the EtO flow to the Abator. Flow from the sterilizers is introduced into the Abator through a flame arrestor on the downstream side of the heater. Flow of contaminated air from other sources such as the aeration room enters the Abator upstream of the prefilter.

Several interlocks are provided to insure safe operation of the system. The interlocks will not allow the EtO feed valve to open unless the following criteria is satisfied:

1. Catalytic bed temperature at 300°F, min.
2. Catalytic bed temperature below 500°F.
3. Air flow rate of 900 CFM, min.
4. Safety blow-out panel properly sealed.
- Optional 5. EtO inlet concentration must be below 5,000 ppm.

(An optional combustible gas detector is required for this interlock).

Once the system is in operation, very little attention is required. Local temperature indications are provided at the heater inlet and outlet. Local pressure differential gauges are provided across the catalytic beds. For more information, see Section 4.0 Instrumentation.

### 3.0 SYSTEM COMPONENTS

The following sections describe the components of the system. Detailed vendor data can be found in Appendix B.

### 3.1 Prefilter

The prefilters are DCI Dustfoe filters with an ASHRAE efficiency of 65%. Donaldson Data Sheet DS-DF-100 in Appendix B describes this standard filter.

It is used to remove particles from the air stream. Particles could blind the surface of the catalyst prohibiting it from permitting the EtO reaction from taking place. Further, particles if flammable, could ignite on the catalyst surface creating a hazard.

### 3.2 Recuperator

This is an air-to-air heat exchanger which is used to preheat the fresh air to the system in order to reduce the heat load of the electric heater. The electric heater should operate very little after initial heat up except near the end of the exhaust cycles from the sterilizer, vacuum pump exhausts, or air wash cycles for the sterilizers (low EtO concentration). The recuperator is approximately 60 percent efficient.

### 3.3 Electric Heater

The electric heater, if chosen, has a 80 KW output and requires 480V 3 phase 60 Hz current. This device is used to heat the circulating air and equipment plus maintain it at 300°F minimum temperature. Other controls are described below.

High temperature thermal cut-out switches with manual reset are included to limit the sheath temperature of the elements.

A temperature controller senses the air temperature and causes the heater to operate accordingly. It is set at 300°F to assure that the minimum temperature of the system

is satisfactory for effective removal of EtO at the catalyst.

### 3.4 Catalyst Bed

The catalyst bed consists of two (2) banks of two (2) DCI Sure-Sorber catalytic filters. The cells provide sufficient catalyst to oxidize the EtO to carbon dioxide and water vapor. Data Sheet 15-00-05 in Appendix B depicts the type of cell to be used.

#### Centrifugal Fan

This is the air mover for the system. It is a centrifugal fan capable of moving 1000 SCFM air at a static pressure of 6" W.G. at ambient temperature. The fan is a high temperature fan capable of operation at temperatures above 500°F. It is equipped with a heat slinger and shaft seal. A flow switch is incorporated to prohibit system operation on low air flow.

Construction is AMCA C which incorporates non-sparking characteristics to the fan.

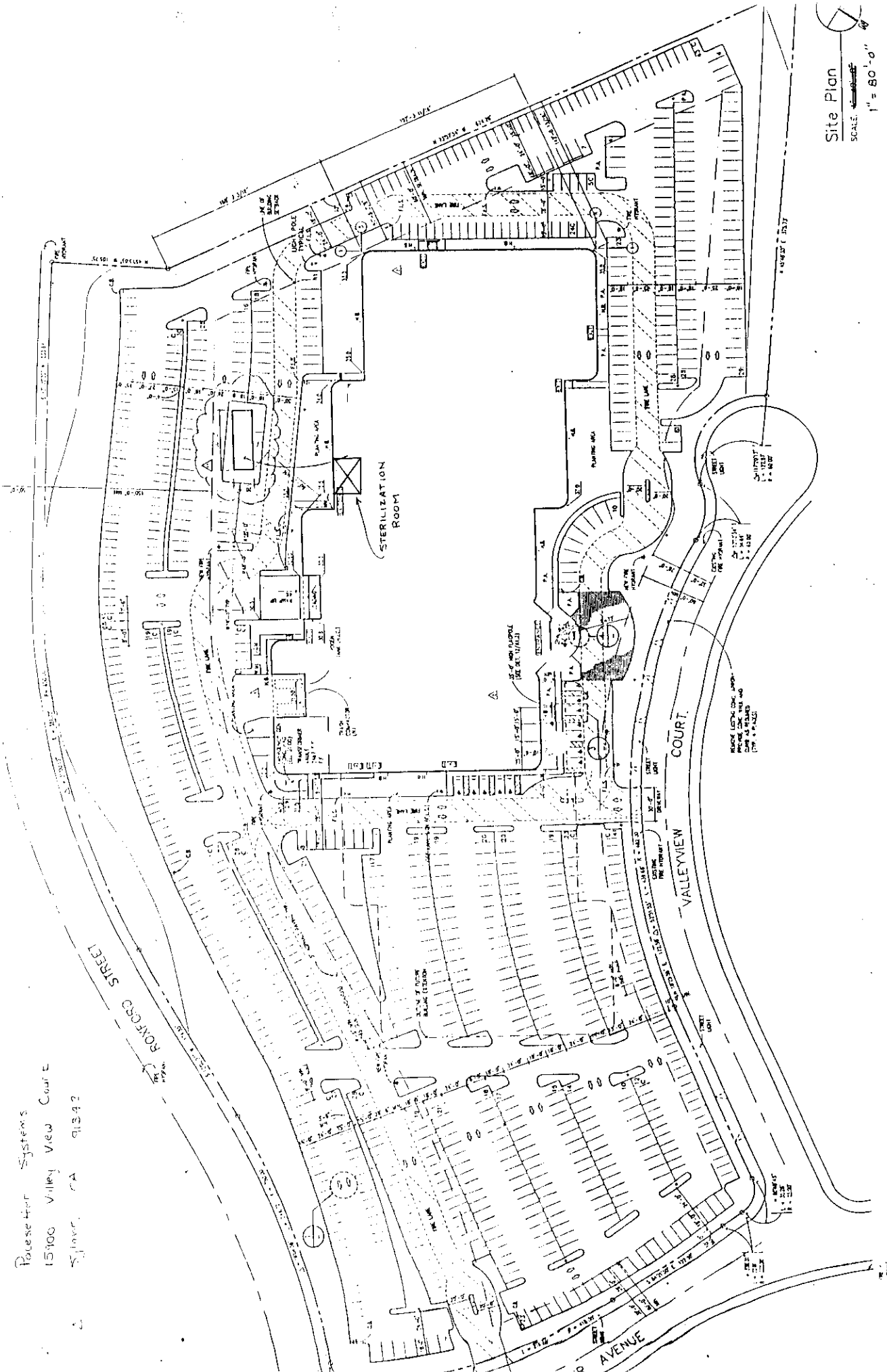
#### Flow Control Dampers

These are modulating dampers used to maintain the flow through the abator or establish recirculation during start-up. The dampers will open, close, or modulate as required to maintain flow and control temperature.

#### EtO Supply and Emergency Vent Valves

These valves control the EtO supply to the system. No EtO will flow unless the temperature of the system is >300°F, the catalyst bed exit temperature is not in excess of 500°F, the concentration of EtO in the system is less than 5,000 PPM (vol.) (optional), and there is adequate flow in the system.

Processer Systems  
15100 Valley View Court  
Sylmar, CA 91342

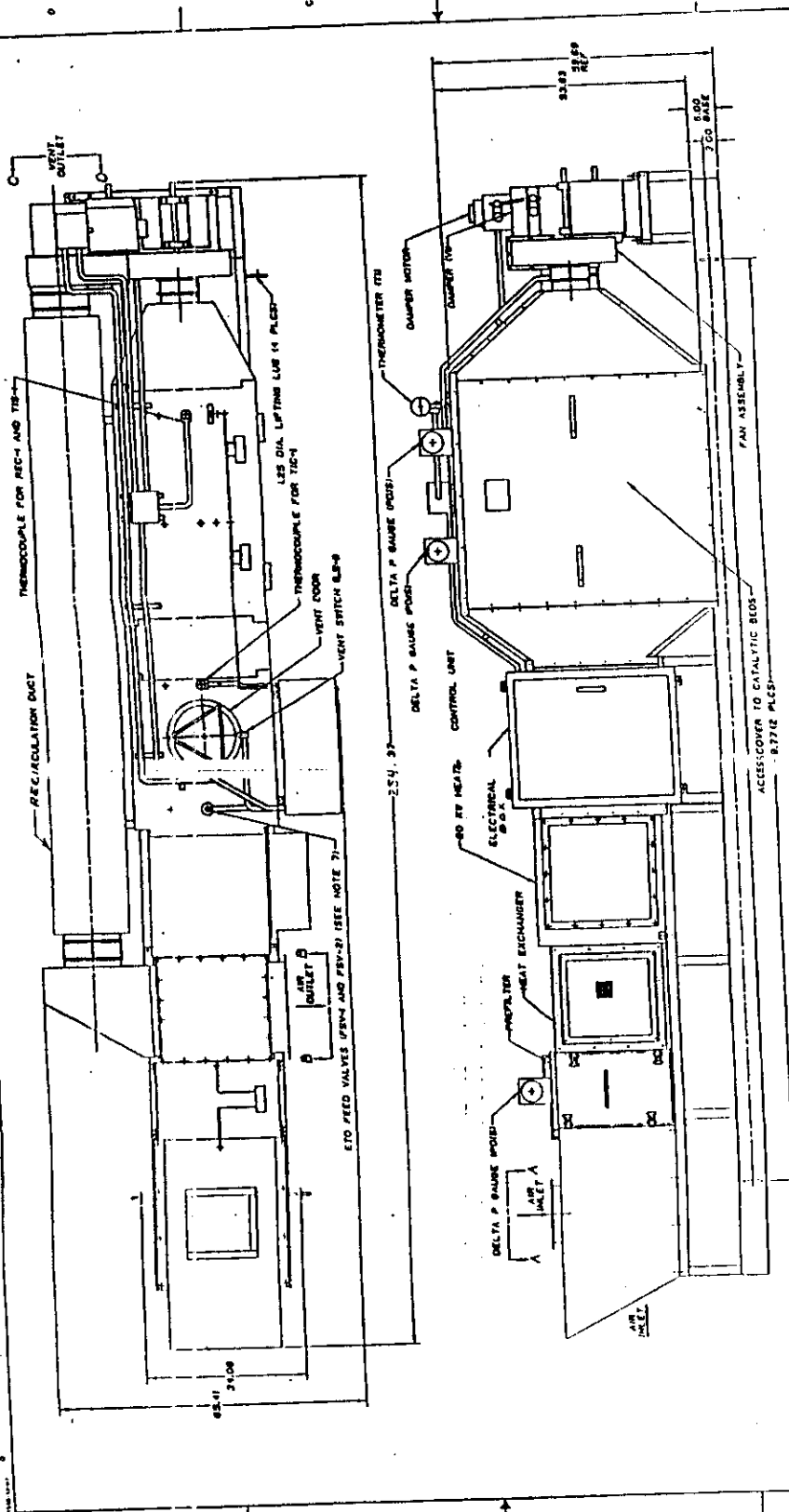


Site Plan  
SCALE: 1" = 80'-0"

Primary Unit

NOV-27-89 14:20  
R. 22  
NONI 2502 CO.  
NONI 2502 CO.

NOV-27-89 14:20  
R. 22  
NONI 2502 CO.  
NONI 2502 CO.



1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100
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CONVENIENCE OUTLET

4200 WBS - EMPTY  
3200 WBS - UNSTATIONS  
4200 3 P, 150 AMPLIFICATION HOURS



**MATERIAL SAFETY DATA SHEET**  
Complies with 29 CFR 1910.1200,  
OSHA Hazard Communication Rule

**MINE SAFETY APPLIANCES COMPANY**  
P.O. Box 429  
Pittsburgh, PA 15230  
Phone: 412/538-3510

Telex: 86-6312

**CHEMICAL IDENTITY**

**LABEL IDENTITY**..... Hopcalite® Catalyst  
**CHEMICAL NAME/SYNONYMS**..... Manganese dioxide and copper oxide mixture  
**FORMULA**.....  $MnO_2-CuO$   
**CAS Registry Numbers**..... 1313-13-9 and 1317-38-0

**PHYSICAL AND CHEMICAL PROPERTIES**

**LCOR, FORM, OODR**..... Dark brown to black granules, odorless  
**STABILITY TO WATER AND AIR**..... Deactivated by water or moisture in the air

**PHYSICAL HAZARD INFORMATION**

**PHYSICAL HAZARD(S)**..... Meets OSHA's criteria for an oxidizer  
**CONDITIONS OR MATERIALS TO AVOID**..... Flammable gases, organic solvents, organics with easily oxidized functional groups, temperatures above 1000°F  
**UNUSUAL FIRE AND EXPLOSION HAZARDS**..... Hopcalite® Catalyst is a non-flammable oxidizing agent; it reacts exothermally and may ignite certain organics.  
**RE EXTINGUISHER**..... Use extinguishers appropriate to other materials involved.  
**SPECIAL FIRE FIGHTING PROCEDURES**..... Wear pressure demand self-contained breathing apparatus with full facepiece and full protective clothing. Disperse Hopcalite® Catalyst and soak with water to prevent reignition.

**HEALTH HAZARD INFORMATION**

**HEALTH HAZARD(S)**..... Repeated inhalation for a period of a few months or longer may be harmful and may cause lung irritation or serious central nervous system disorders.  
**SIGNS AND SYMPTOMS OF EXPOSURE**..... The symptoms of manganese poisoning are headache, weakness, sleeplessness, personality changes, hearing and vision problems, mental confusion. In the advanced stages, the symptoms are similar to those of Parkinsonism. Copper oxide may cause lung irritation.

PRIMARY ROUTE(S) OF ENTRY..... Inhalation

TARGET ORGANS..... Central nervous system, lungs

MEDICAL CONDITIONS GENERALLY RECOGNIZED  
AS BEING AGGRAVATED BY EXPOSURE..... No information

EXPOSURE LIMITS (OSHA PEL, ACGIH TLV,  
OTHERS USED OR RECOMMENDED)..... OSHA Standard - 6 mg/m<sup>3</sup> (ceiling) manganese; 1  
mg/m<sup>3</sup> copper dusts and mists. ACGIH TLV-TWA - 5 mg/m<sup>3</sup> (ceiling) manganese, as Mn dust  
and compounds; 1 mg/m<sup>3</sup> copper dusts and mists, as Cu

CARCINOGENICITY DATA..... No information; chemical is not listed in  
National Toxicology Program (NTP) Annual Report on Carcinogens, not found to be a  
potential carcinogen in the International Agency for Research on Cancer (IARC)  
Monographs, not listed by OSHA.

EMERGENCY AND FIRST AID PROCEDURES..... Move personnel to fresh air. Call a  
physician.

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### SAFE HANDLING AND USE

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HYGIENIC PRACTICES..... Use with adequate ventilation. Avoid breathing  
dust. Remove dust fines from air or wear recommended respirator.

PROTECTIVE MEASURES DURING  
REPAIR AND MAINTENANCE OF CONTAMINATED  
EQUIPMENT..... Wear recommended protective gear.

STORAGE..... Store in a dry place away from incompatible  
materials.

SPILL OR LEAK CLEANUP PROCEDURES..... Scoop into metal container. Cover loosely.  
Remove to chemical disposal area. Deactivate by soaking with water. Flush spill area  
with water.

WASTE DISPOSAL..... Landfill

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### CONTROL MEASURES

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PERSONAL PROTECTIVE EQUIPMENT  
WHEN EXPOSURE IS POSSIBLE..... Chemical protective goggles, NIOSH/MSHA  
approved filter-type respirator, rubber gloves, coveralls

WORK PRACTICES..... Keep away from organic solvents and organics  
containing easily oxidized functional groups. Keep container closed; moisture will  
reduce the catalytic activity.

Hopcalite® Catalyst  
Material Safety Data Sheet

ENGINEERING CONTROLS..... Provide general and local ventilation. Exclude organic vapors from work area.

DATE OF PREPARATION..... 10/15/85